Editor’s Perspective

Barriers to the Use of Patient-Reported Outcomes in Clinical Care

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I am conflicted in writing this Editorial Perspective. For over 20 years, I have been advocating for greater inclusion of patients’ perspectives of their disease into the outcomes of clinical trials, into the methods for quality assessment/improvement, and as a basis for shared medical decision making. I have developed disease-specific measures for coronary artery disease, heart failure, and peripheral artery disease.1–3 Although some may say this perspective is self-serving, I think I have gained important insights into the barriers of health status assessments and wish to articulate the challenges I see.

Patient-reported outcomes (PROs) quantify patients’ perspectives about the frequency and severity of their symptoms, how their disease impacts their functioning, and the degree to which it limits their quality of life. Over the past several decades, numerous PROs, both generic and disease-specific, have been created, and the methodology for creating such measures has become increasingly codified. A PRO should be valid, reproducible over time in stable patients, and sensitive to clinical changes when they occur.4 Accordingly, PROs can be selected for a variety of conditions that are not only valid, reliable, sensitive to changes in disease status (or treatment), but also prognostic of clinical events, costs, and mortality. Moreover, they are probably the best assessment of the impact of a disease on patients’ health status and are far more reproducible than clinician-reported outcomes, such as the New York Heart Association (NYHA) or the Canadian Cardiovascular Society Classification.5,6 Yet, despite over a decade of calls for these measures to be included in routine clinical care, they are seldom used.7

In November 2013, the Patient-Centered Outcomes Research Institute held a 2-day conference in which multiple healthcare stakeholders assembled to discuss the importance of including PROs in electronic health records and clinical care. Numerous stakeholders, including the National Quality Forum, the Federal Drug Administration and patient advocates, emphasized how much they value the patients’ perspectives, and all strongly endorsed their use in quality assessment, drug/device approval, and clinical care. Yet, despite this strong support for the routine use of PROs in clinical care, they are seldom used. Even clinician-reported estimates of patients’ health status using the NYHA are seldom completed on each and every visit. For example, a recent analysis from the American College of Cardiology’s outpatients registry, PINNACLE, found that the NYHA was recorded in just over a third of clinical visits for heart failure patients (36.8%) in 2012, and that among 1242 providers, a quarter of them recorded it in none of their patients, whereas the top 10% recorded it in all of their clinical visits. Essentially, none of the practices routinely used Kansas City Cardiomyopathy Questionnaire (KCCQ) or another PRO, relying instead on clinicians’ assessments of heart failure patients’ health status. The question why PROs have not been adopted is important, and I think the research community must address key barriers if they are to be adopted in clinical practice. I think the steps required to capture the patients’ voice in clinical care, through PROs, require that we address the ‘vowels of adoption—that the PROs be Actionable, Efficient, Interpretable, Obligatory, and User-friendly.

To be useful in clinical care, a PRO must be actionable. That is, based on the results of the questionnaire, the clinician will treat or counsel the patient differently. For example, in the setting of coronary disease, more symptomatic patients warrant increased antianginal therapy or revascularization. Yet, without systematically collecting PRO data, the symptom burden of angina may not be apparent to physicians. For example, in a national study conducted in Australia, primary care doctors were asked to have 10 to 20 consecutive patients with coronary disease complete the self-administered Seattle Angina Questionnaire.8 The frequency of patients with weekly angina, a severe burden of symptoms that could clearly warrant more aggressive care, ranged from 0% to 100% across practices. This means that in some primary care practices all of their patients had reasonably good symptom control, whereas in others all of their patients reported having angina more than once a week. Importantly, many physicians felt that their patients were optimally controlled, even when the patient reported weekly (48% of physicians thought the patients were optimally controlled) and daily (37% of physicians reported their patients were optimally controlled) angina. The access to patients’ report of their symptom burden could help flag those with worse symptom control whose anti-anginal medications could be increased or who could be referred to a cardiovascular specialist. In the future, there could be risk-adjustment models available to share with patients the expected benefits of alternative treatments (eg, medication intensification, percutaneous coronary intervention, or bypass surgery) on their symptoms, function, and quality of life. However, without the routine collection of PRO information, models that could support shared medical decision making cannot even be developed.
An additional barrier to the routine use of PROs is that they support improved practice efficiency. In every clinical visit, it is the challenge of the provider both to establish a rapport with patients and to serve as a counselor for a myriad of healthcare-related issues. To do so, it is important for the clinician to rapidly understand the current impact of the disease on patients’ lives. Health status measures can serve this role. Disease-specific PROs reproducibly ask relevant questions about how a disease impacts the symptoms, function, and quality of life of the patient. Summarizing these into a score should increase the efficiency of history taking and enable the clinician to rapidly zero in on any change in health status or, if none has occurred, to confirm this and use the scarce time available to address other health or personal issues confronting the patient. Of course, this efficiency can only occur if the PROs are readily interpretable by the clinician.

I think that interpretability is the key challenge inhibiting the broader use of PROs. In the 1970s, many clinicians had difficulty understanding the clinical significance of a systolic blood pressure of 220 mmHg as compared with one that was 120 mmHg. Similarly, in the 1980s, clinicians had little understanding of the difference between a low-density lipoprotein level of 170 and 70 mg/dL. However, with the emergence of observational registries and clinical trials demonstrating the prognostic importance of different blood pressure or cholesterol levels, as well as the benefits of reducing these levels on outcomes such as death, stroke, and myocardial infarction, clinicians became facile at understanding how to interpret a patient’s blood pressure or low-density lipoprotein level. PROs, which are often transformed to a scale of 0 to 100, do not currently provide any intuitive interpretation for clinicians. I think that researchers need to begin supporting the ready clinical interpretability of health status measures. These can be done by translating the scores into more familiar clinical benchmarks and by showing the prognostic importance of such scores. The Figure shows 1 approach that our group is considering so that we can better translate the clinical and prognostic importance of the overall summary score from the KCCQ.

The figure reveals that today the patient has a KCCQ score of 74, and it also shows what that score means in terms of a qualitative statement (that they are doing good with respect to their heart failure) and how that score relates to a more familiar metric of the NYHA (class II). Moreover, it shows the prognostic significance of that score in terms of 1-year death/hospitalization rates. On comparing this score with a previous one, changes in patients’ health status are readily apparent, along with the improvement in their prognosis. As a prototype, this approach should provide a lot of information about a patient even before the doctor takes their history. Much more work is needed, however, to refine the output, implement it into routine clinical care, and demonstrate that the incorporation of such a PRO can improve care and outcomes.

A fourth step to support the use of PROs in routine clinical care is to integrate them into routine workflow, something that could readily happen if they were obligatory. To date, payers do not demand evidence that the care we provide is conferring value from the perspective of patients. In fact, the National Quality Forum, after initially approving the performance measures for patients’ symptoms and function in coronary disease and heart failure, removed them from their list of approved measures in 2011. Recently, in the setting of transcatheter aortic valve replacement, the Centers of Medicare and Medicaid Services have mandated baseline and follow-up use of the KCCQ as a criterion for payment. Although it makes sense to routinely assess the health status of patients for better healthcare management, I think that without an external incentive, ideally linked to payment, the routine use of PROs will never rise to the top of a healthcare system’s priority list.

The final step to support adoption is user-friendliness. Historically, PROs were time-consuming. Developers should work to reduce the length of these instruments, while preserving their psychometric properties. Recently, our group reduced the 19-item Seattle Angina Questionnaire to 7 items, and the 23-item KCCQ to 12. These simple, 1- to 2-page forms take <2 minutes to complete. It seems imminently feasible to have patients complete these at each office visit, as is currently done at the Cleveland Clinic (personal communication, Rory Hachomavitch). Alternatively, patients could complete these through a web portal before their visit. Then, the scores would be available to the clinician before entering the room and evaluating the patient. As a standardized history, the clinician would be able to know instantly how the patient was doing with respect to their disease and how it had changed since the last visit (see the Figure). Such a tool could increase the efficiency of a routine outpatient visit. Similarly, if the instruments were completed over the web as part of a routine follow-up, patients could be instructed to proactively call their health team in case of deterioration in their health status, and thus patients could become important co-managers of their disease.

The fact is that PROs quantify a critical element of patients’ experiences with care, and because patients’ health status can often be improved with proper awareness by clinicians, PROs can be an important component of routine healthcare. Once
these are routinely used, providers can use this information to better manage their patients; payers can use this information to ensure they are getting value for the expenses they incur; and health services researchers can use this information to examine disparities, build risk models and shared decision-making tools, and develop new insights into how best to improve health. However, the research community needs to meet the challenges articulated in this article if we are to really support the feasibility and value of integrating systematic PRO collection into routine clinical care. Overcoming these challenges can lay the foundation for more patient-centered care as well as improving the quality of healthcare.

Disclosures

None.

References


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